

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION**

**KINETIC CONCEPTS, INC., §
KCI LICENSING, INC., KCI USA, INC. §
and WAKE FOREST UNIVERSITY §
HEALTH SCIENCES §
§
VS. §
§
MEDELA AG and MEDELA, INC. §**

**CIVIL ACTION NO.
SA-08-CV-00087-WRF**

ADVISORY TO THE COURT

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The Court committed grave error when it completely disregarded the jury's factual findings in *Kinetic Concepts, Inc., et al. v. Bluesky Medical Corp., et al.*, No. SA-08-CV-102 (W.D. Tex.) (the "Smith & Nephew Case"), applied the wrong standard of review, and substituted its own judgment for that of a conscientious jury, which carefully considered all of the evidence throughout a month of trial and deliberations. The Court's October 19, 2010, Advisory to the Parties (Dkt. No. 153, the "Advisory") suggests that the Court may further compound that error by treating the Smith & Nephew ruling as automatically dispositive of patent claims in this case, most of which were not at issue in the Smith & Nephew case, and are still presumed valid. The Advisory is premised on a fundamental misunderstanding of patent law that is also evidenced in the Smith & Nephew judgment, i.e., that a Court can invalidate entire patents (or groups of patent claims) without considering the individual elements of each asserted claim. This premise is simply wrong.

Moreover, summary judgment based on issue preclusion or on the merits is unsupported by the facts and would improperly contravene the Federal Circuit's findings against Medela in *Kinetic Concepts, Inc. v. Blue Sky Medical Group, Inc.*, 554 F.3d 1010 (Fed. Cir. 2009) ("*Blue Sky*"). It is *Medela* that should be precluded from attacking validity on the issues that were before the Federal Circuit in *Blue Sky*. Indeed, Plaintiffs *cannot* be bound by the findings made by this Court that contravene binding Federal Circuit precedent.

Because it would be improper for the Court to invalidate the claims at issue here without at least permitting additional, potentially extensive, proceedings, and because the Smith & Nephew judgment is unprecedented and unsupportable, Plaintiffs request that this case be stayed pending appeal of that judgment.

I. Most of the Claims Asserted Against Medela in the Present Case Were Not Invalidated in the Smith & Nephew Case and Are Presumed Valid

The Court's Advisory proceeds from the incorrect premise that the Smith & Nephew Judgment invalidated "both the '081 *patent* and the '651 *patent*" in their entirety. *See* Advisory, at 1 (emphasis added). But only the validity of claims 2 and 5 from the '081 Patent and claims 42, 109, 116, and 121 from the '651 Patent (the "Litigated Claims") was disputed at the Smith & Nephew trial, and only those claims were invalidated by the Court's judgment. It is a fundamental principle of patent law that "[e]ach claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims." 35 U.S.C. § 282; *see also Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1378 (Fed. Cir. 2009) ("Each issued patent claim is presumptively valid.").

Most of the claims still at issue in the present case were not invalidated by the Smith & Nephew judgment and, therefore, cannot be summarily disposed of. In particular, claims 1, 3, 8, 12, 18, 23, 24, 27, 35, 46, 47, 71, 111, 123, 124, and 125 of the '651 Patent and claims 42 and 44 of the '046 Patent (the "Non-Litigated Claims") were not adjudicated. Each of these claims is independently presumed to be valid under the Patent Act, regardless of the judgment's impact on the Litigated Claims. 35 U.S.C. § 282; *Martek*, 579 F.3d at 1378; *see also Applied Materials, Inc. v. Gemini Research Corp.*, 835 F.2d 279, 281 (Fed. Cir. 1987) (finding that "[t]he district court erred in not giving proper weight to the patent's presumption of validity" in invalidating claims based on collateral estoppel arising from a related patent, and stating that "[t]he presumption of validity carries with it the assumption that the evidence considered by the PTO when granting the patent was material.").

II. Defendants Are Not Entitled to Summary Judgment of the Non-Litigated Claims Based on Issue Preclusion

Plaintiffs' presumptively valid Non-Litigated Claims cannot be summarily disposed of under the doctrine of issue preclusion. Courts have held that issue preclusion may apply to non-litigated claims, but only when those claims are substantially identical to invalidated claims. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1136-37 (Fed. Cir. 1985). The purpose for doing so is to preclude relitigation of multiple claims that are merely "differently worded." *See Bourns, Inc. v. U.S.*, 537 F.2d 486, 492 (Ct. Cl. 1976); *Medinol Ltd. v. Guidant Corp.*, 341 F. Supp. 2d 301, 314 (S.D.N.Y. 2004). But that is not the case here. The Non-Litigated Claims raise different issues relating to patentability than those addressed by the Smith & Nephew judgment, and are more than simple rewordings of the Litigated Claims. Moreover, entry of judgment based on issue preclusion would be premature because expert discovery has not been completed in this case and Plaintiffs must be given the opportunity to conduct discovery and present evidence regarding the differences between the Litigated Claims and the Non-Litigated Claims.

A. Determination of Whether Issue Preclusion Applies to Non-Litigated Claims Requires a Multi-Step Analysis

The law is clear that the Court cannot simply enter summary judgment against Plaintiffs on the Non-Litigated claims based on the Smith & Nephew judgment. Under Fifth Circuit law, issue preclusion can be found only when: "(1) the identical issue was previously adjudicated; (2) the issue was actually litigated; and (3) the previous determination was necessary to the decision." *Pace v. Bogalusa City School Bd.*, 403 F.3d 272, 290 (5th Cir. 2005).

A multi-step approach is applied to determine if the validity of non-litigated patent claims raises "identical" issues for purposes of issue preclusion. First, the non-litigated claims are compared with the invalid claims and, if they are *identical* in scope, issue preclusion applies. *Medinol*, 341 F. Supp. 2d, at 315 (citing *Westwood Chem., Inc. v. U.S.*, 525 F.2d 1367, 1375 (Ct.

Cl. 1975)). If *any* substantive differences exist between the claims, however, it must then be determined whether the substantive differences present new issues as to any of the factual inquiries underlying obviousness set out in *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). *Interconnect*, 774 F.2d at 1136; *Medinol*, 341 F. Supp. 2d, at 315. It is Defendants' burden to show that no new factual issues are presented by the non-litigated claims as a matter of law, otherwise issue preclusion *cannot* apply. *Bourns*, 537 F.2d at 493 n.6. (holding that it is a defendants' burden to show that there are no genuine issues of material fact relevant to the determination of whether identical issues are presented by non-litigated claims). But even if Defendants can show that the differences in the non-litigated claims were indisputably known in the prior art, it is still necessary for Defendants to establish that the non-litigated claims are substantially similar as a matter of law after the importance of the differences to the *combination as a whole* is assessed. *Medinol*, 341 F.Supp.2d, at 315 (citing *Westwood*, 525 F.2d at 1375).

The last step in the analysis—considering the claimed invention as a whole—is crucial because the invalidated claims *are not prior art*. See *Interconnect Planning*, 774 F.2d, at 1137. It is improper to compare only the *differences* between the adjudicated claims and the non-adjudicated claims with prior art that is pertinent only to those differences. *Id.* In other words, when there are additional elements in the non-litigated claims that distinguish the invention as a whole from the prior art, litigation of those claims cannot be precluded merely by showing that the additional elements are disclosed somewhere in the prior art. *Medinol*, 341 F. Supp. 2d at 315. “A domino approach in which each successively narrower claim is compared with the one before it, not with the prior art, is inappropriate since it improperly gives prior-art effect to the subject matter of an invalid claim.” *Interconnect Planning*, 774 F.2d at 1137 (quoting *Bourns*, 537 F.2d at 493).

B. Substantial Differences Exist Between the Litigated Claims and Non-Litigated Claims, Making Summary Judgment Based on Issue Preclusion Inappropriate.

The Non-Litigated Claims present issues regarding differences between the prior art and the Non-Litigated Claims as a whole that were not raised or resolved in the Smith & Nephew Case. Below, Plaintiffs set out *some* of these differences to illustrate to the Court that the Non-Litigated Claims cannot be summarily disposed of based on issue preclusion.

**(i) Maintaining reduced pressure until the wound has progressed toward a “cessation of partial thickness burn progression”
(’046 Patent, Claim 42)**

Claim 42 of the ’046 Patent covers a new method for maintaining negative pressure on a burn to cease progression of the depth of the burn. This is not a simple rewording of any of the Litigated Claims, but an entirely new invention. The ’046 Patent specification specifically addresses the importance of the invention in Claim 42: “The progression of partial thickness burns to deeper burns is a major problem in burn therapy. The ability to control or diminish the depth of burns greatly enhances the prognosis for burn patients and decreases morbidity resulting from burns.” ’046 Patent, col. 2, ll. 35-39. The inventors discovered that applying and maintaining negative pressure on a partial thickness burn soon after its infliction dramatically helped prevent the burn from progressing to a deeper wound. ’046 Patent, col. 17, ll. 11-16 (Example 3B).

None of the claims asserted in the Smith & Nephew Case are limited to the treatment of burns, and none of the prior art in that case was analyzed to determine if treatment of partial thickness burns with negative pressure was known in the art. Claim 42, therefore, raises entirely new issues relating to patentability, making summary judgment of invalidity inappropriate.

**(ii) Maintaining reduced pressure until the wound has progressed toward “at least a 50% reduction in bacterial density in the wound”
(’046 Patent Claim 44)**

Similarly, claim 46 of the '046 Patent covers a new invention separately addressed and emphasized in the specification, and is not simply a rewording of any of the Litigated Claims. Claim 46 recites a method for applying and maintaining negative pressure on an infected wound to reduce the bacterial burden in the wound by half. In the Summary of the Invention, the inventors describe this method as a way “to reduce the bacterial density of an infected wound to the point at which surgical closure can be attempted.” '046 Patent, col. 4, ll. 26-32.

None of the Litigated Claims claim reducing bacterial density in an infected wound by maintaining negative pressure, and none of the prior art addressed in the Smith & Nephew Case discloses bacterial reduction in wounds as claimed. The method of claim 46 is not referring to draining pus with suction as in the Bagautdinov and Davydov references. Instead, the claim covers the inventors' discovery that applying and maintaining negative pressure can reduce the amount of *bacterial organisms* in the tissue. This is clear from the specification, which describes “bacterial density” in terms of the number of “bacterial organisms per gram of tissue.” '046 Patent, col. 13, ll. 37-39. Moreover, an experiment described in the patent relating to this claim describes applying a negative pressure device to a pus-free wound immediately after it is inoculated with *Staphylococcus aureus*—not simply using suction to remove pus as in Bagautdinov. '046 Patent, Example 2, col. 15, ll. 42-60.

(iii) **“Deforming said cover so as to exert tension upon the tissue surrounding the wound”
('651 Patent Claim 47)**

Claim 47 of the '651 Patent claims a device that is configured to “exert tension upon the tissue surrounding the wound,” a limitation that is not specifically recited in any of the Litigated Claims. In the '081 Patent, the inventors explain that “[t]he use of negative pressure provides tension on th[e] border tissue that causes accelerated tissue migration.” '081 Patent, col. 2, ll. 49-53. The “tension” limitation in claim 47 is, therefore, an important claim element that

distinguishes the claim from the prior art in ways that were not examined in the Smith & Nephew Case.

(iv) **“One piece flexible adhesive cover” (’651 Patent Claim 1) and
“Continuous uninterrupted adhesive seal” (’651 Patent Claim 8)**

Claims 1 and 8 of the ’651 Patent each include important limitations that are not recited in any of the Litigated Claims. A review of the prosecution history will show that the “*one piece flexible adhesive cover*” limitation and the “*continuous uninterrupted adhesive seal*” limitation are material distinctions because both of these limitations were specifically added to distinguish Zamierowski’s two-piece cover. Since neither Bagautdinov nor Zamierowski includes a “one piece flexible adhesive cover” or a “continuous uninterrupted adhesive seal,” these limitations raise new issues regarding obviousness that were not addressed with respect to the Litigated Claims.

C. **Summary Judgment of Non-Litigated Claims Based on Issue Preclusion Would Be Improper**

Plaintiffs submit that the distinctions between the Litigated and Non-Litigated Claims set out above, as well as others, are sufficient to preclude the application of issue preclusion. But, at the very least, these distinctions are sufficient to show that the Non-Litigated Claims cannot simply be invalidated based on the Smith & Nephew Judgment without giving Plaintiffs the opportunity to conduct discovery, submit briefs, and present evidence to the Court to demonstrate the importance of these distinctions, and others, to the Non-Litigated Claims as a whole. *See e.g. Westwood*, 525 F.2d at 1373 n.8 (noting that “motions, hearings, and briefs” are needed to evaluate the potential application of collateral estoppel to non-litigated claims). This is especially true in light of the presumption of validity of the Non-Litigated Claims and the fact that it is *Defendants’* burden to establish that identical issues are presented by the Litigated Claims and the Non-Litigated Claims. *Bourns*, 537 F.2d at 493 n.6.

III. Summary Judgment of Obviousness on the Merits Is Also Inappropriate

In addition to the numerous differences between the Non-Litigated Claims and the Litigated Claims that preclude summary judgment on issue preclusion, there are additional reasons why the Court cannot enter summary judgment against Plaintiffs on the merits. When the issue shifts from issue preclusion to the merits of obviousness, the content of the Litigated Claims is no longer relevant at all. *See Interconnect Planning*, 774 F.2d at 1141 (concluding that an adjudicated claim was “of no further moment” in a summary judgment analysis after it was determined to be not substantially identical to a reissue claim). Instead, the Non-Litigated Claims must be separately analyzed in accordance with the *Graham* factors, and a reason for combining the prior art, “other than hindsight gleaned from the invention itself,” to arrive at the *new* inventions must be found. *Id.* at 1141, 1143. Importantly, this analysis includes applying the “secondary considerations” of non-obviousness to the Non-Litigated Claims. *Id.* at 1144 (vacating summary judgment of obviousness of claims in a reissue patent in part due to district court’s failure to consider the secondary considerations of market success and contemporaneous reaction).

The Court cannot forego this obviousness analysis on the theory that Plaintiffs are somehow bound by the Court’s findings in *Smith & Nephew*, because giving preclusive effect to such findings actually favors *Plaintiffs* in light of *Blue Sky*. In that case, the Federal Circuit made findings contrary to those of the *Smith & Nephew* judgment on the key issue of whether the prior art discloses treating “wounds.” For example, the Federal Circuit found support for the conclusion that the Chariker-Jeter prior art, including testimony from Dr. Chariker about an alleged public use of the system on a wound without a fistula, *does not* disclose treating a wound with negative pressure. *Blue Sky*, 554 F.3d at 1020 (“Based on our review of the record, we find that the testimony of KCI’s witnesses was sufficient to allow the jury to reach the conclusion that

the Chariker-Jeter method was not used to ‘treat a wound with negative pressure’ as required by the claims”). This directly contradicts this Court’s finding that the jury in the Smith & Nephew Case (which was presented with substantially the same testimony from the same witnesses) could not have properly found that Chariker-Jeter fails to disclose treating a wound with negative pressure. In addition, the Federal Circuit found support for the conclusion that draining pus from an *exposed* purulent cavity, as in Davydov, is not treating a wound with negative pressure. *Id.* at 1020. This is contrary to the conclusion in the Smith & Nephew judgment that Bagautdinov treats “wounds” merely because the purulent cavities he drains are exposed. Because the Federal Circuit’s findings carry more weight than the District Court’s findings,¹ Medela, not Plaintiffs, should be precluded from relitigating the underlying factual issues supporting validity.

Plaintiffs contend that the claims asserted against Medela are not obvious in light of the differences between the claims and the prior art, the lack of any reason to combine the prior art references to arrive at the claimed inventions, the overwhelming evidence regarding secondary considerations of non-obviousness, and the Federal Circuit’s findings in *Blue Sky*. And Plaintiffs are entitled to have a jury make these factual determinations. But even if the Court is of the opinion that the Smith & Nephew judgment raises questions regarding the validity of the Non-Litigated Claims, it would be improper to summarily invalidate those claims without allowing for briefing, an evidentiary hearing, and the opportunity to complete discovery. Regardless of the Smith & Nephew judgment, the Non-Litigated Claims are still presumed valid and it is Defendants’ burden at the summary judgment stage to “submit such clear and convincing evidence of facts underlying invalidity that no reasonable jury could find otherwise.” *Trimed*,

¹ Not only is the Federal Circuit the governing appellate court in this and all related matters, but both Plaintiffs and Defendants in the present matter were parties to the *Blue Sky* case. *See Test Masters Educ. Servs. v. Singh*, 428 F.3d 559, 575 n.6 (5th Cir. 2005) (finding mutual collateral estoppel more likely to bind a party than non-mutual collateral estoppel).

Inc. v. Stryker Corp., 608 F.3d 1333, 1339-40 (Fed. Cir. 2010) (quoting *SRAM Corp. v. AD-II Eng'g, Inc.*, 465 F.3d 1351, 1357 (Fed. Cir. 2006)). If Defendants cannot meet this burden, which they cannot, Plaintiffs are entitled to the jury trial they have demanded.

IV. Court Should Stay the Proceedings

The Court cannot summarily invalidate the claims asserted in this case without further, potentially extensive, proceedings. Instead, Plaintiffs propose that the Court continue the stay presently in effect pending appeal of the Smith & Nephew Case. While the Smith & Nephew Judgment cannot preclude litigation of the Non-Litigated Claims, the outcome of the appeal of the Judgment is very likely to provide guidance regarding how the present case should proceed. Moreover, continuing the stay is particularly appropriate in this case due to the highly unusual posture of the Smith & Nephew Case. Specifically, while the Litigated Claims were invalidated by the Court, (i) some of the claims had previously been found valid over some of the *same* prior art at issue in the Smith & Nephew Case in a judgment upheld by the Federal Circuit; (ii) the validity of all of the claims over the same prior art at issue in the Smith & Nephew Case was confirmed by the U.S. Patent and Trademark Office following reexaminations initiated by Smith & Nephew, strengthening the presumption of validity; and (iii) the jury in the Smith & Nephew Case determined that all of the Litigated Claims are valid and answered special interrogatories tracking the *Graham* factors supporting their verdict. In light of these prior determinations, Plaintiffs submit that it would be inequitable to apply the Smith & Nephew judgment to the present case and the Non-Litigated Claims before the Federal Circuit addresses the unique circumstances surrounding the Court's Judgment. *See Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 333-34 (1971) (holding that collateral estoppel decision in the context of patent validity "will necessarily rest on the trial courts' sense of justice and equity").

Dated: November 5, 2010

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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing document was filed electronically in compliance with Local Rule CV-5(a). As such, this Motion was served on all counsel who are deemed to have consented to electronic service. Local Rule CV-5(b)(1). Pursuant to Fed. R. Civ. P. 5(a)-(d) and Local Rule CV-5(b)(2), all other counsel or record not deemed to have consented to electronic service were served with a true and correct copy of the foregoing by email and/or fax, on this the 5th day of November, 2010.

A handwritten signature in blue ink that reads "R. Laurence Macon".

R. LAURENCE MACON